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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/461,537 | 12/15/1999 | JOHN C. ROYER | 4216.260-US | 3928 |
| 25907 | 7590 | 10/06/2005 | EXAMINER | |
| NOVOZYMES, INC. 1445 DREW AVE DAVIS, CA 95616 | | | MARVICH, MARIA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/461,537

Applicant(s)

ROYER ET AL.

Examiner

Maria B. Marvich, PhD

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 8/24/05.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

530

Art Unit: 1633

DETAILED ACTION

This office action is in response to an amendment and a request for continued examination filed 8/29/05. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/29/05 has been entered.

Claims 1-26 have been cancelled. Claims 27-28 have been amended. Claims 29-30 have been added. Claims 27-30 are pending in the application.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Claim Objections

Claims 29 and 30 are objected to because of the following informalities: Claims 29 and 30 recite that the cell is the "host cell of NRRL 30747". It would be remedial to recite that the cell is the "host cell deposited under NRRL 30747".

Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and

Art Unit: 1633

useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 15 and 16 of U.S. 6,893,839. **This is a new rejection.**

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims 1, 2, 15 and 16 of U.S. 6,893,839. That is, the cited claims of U.S. 6,893,839 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, the instant claims and U.S. 6,893,839 claims recite a *Fusarium*

Art Unit: 1633

venenatum cell that is specifically ATCC 20334 and its use for the production of heterologous proteins.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the U.S. 6,893,839 application, then two different assignees would hold a patent to the claimed invention of U.S. 6,893,839 application, and thus improperly there would be possible harassment by multiple assignees.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

Applicants recite a genus of non-toxic, non-toxigenic, non-pathogenic *Fusarium venenatum* host cells.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed

Art Unit: 1633

correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

Applicants claim a method for producing a heterologous protein comprising culturing non-toxic, non-toxigenic, non-pathogenic *Fusarium venenatum* host cells comprising a nucleic acid sequence encoding the heterologous protein. The specification is drawn to methods of producing heterologous proteins using any non-toxic, non-toxigenic, non-pathogenic recombinant *Fusarium* host cell in the section Discolor (see e.g. page 2, line 25-31). This is a large taxonomic group of organisms that are listed in page 4, line 19-26. In a specific embodiment, the host cells are *Fusarium graminearum*. Specific growth characteristics and morphological characteristics of this species are provided on page 5, line 24-page 6, line 3. More specifically, the strain of *Fusarium* contemplated for use in the instant invention is ATCC 20344 more recently deposited as NRRL 30747. Applicants have provided evidence in the form of a Declaration (filed 5/16/00) to correct the classification of the cells comprising ATCC 20334 or NRRL 30747 to *Fusarium venenatum*.

The specification teaches "the term "*Fusarium graminearum*" refers not only to organisms encompassed in this species, but also includes those species which have previously been or currently are designated as other species in alternate classification schemes, but which possess the same morphological and cultural characteristics defined above, and may be synonymous to *F. graminearum*" (page 6, line 9-13). Therefore, the claimed host cells in light of the specification encompass a broad genus of cells. An adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is the knowledge

Art Unit: 1633

in the prior art and/or a description as to the availability of a representative number of species of claimed nucleic acid sequences. In the instant case, applicants have only demonstrated a single isolate that is non-toxic, non-toxigenic, and non-pathogenic. The prior art teaches that these cells encode toxic proteins naturally. As well, the prior art does not teach other isolates of *Fusarium venenatum* or any other naturally occurring cells that meet the broad definition of potential host strains are non-toxic, non-toxigenic and non- pathogenic. Furthermore, applicants have not demonstrated that variance of this strain would result in a cell that is functionally similar to disclosed ATCC 20334. As well, the specification fails to convey the relevant identifying characteristics of ATCC 20334 such that the structural requirements of the cell can be envisioned. Therefore, the relationship between structure and function is unclear as neither applicant nor the prior art provide a correlation between the ATCC 20334 and the ability to be non-toxic, non-toxigenic and non-pathogenic in order to produce heterologous proteins. Given the large size and diverse nature of the potential cells and the inability to determine which will also possess the recited characteristics, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of ATCC 20334 or NRL 30747 would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Conclusion

Claims 27-30 are rejected.

Art Unit: 1633

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633

September 27, 2005



DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER